



## UNITED STATES DEPARTMENT OF COMMERCE

## Patent and Trademark Offic

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/426,792 10/22/99 MANGANO D 9114-004-999

020583 HM12/0407  
PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711

EXAMINER

SPIVACK, P

ART UNIT	PAPER NUMBER
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1614

DATE MAILED:

04/07/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

*JNDC**JNCA*

<b>Office Action Summary</b>	Application No. <b>09/426,792</b>	Applicant(s) <b>Mangano</b>
	Examiner <b>Phyllis G. Spivack</b>	Group Art Unit <b>1614</b>

Responsive to communication(s) filed on Jan 7, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-16 and 49-52 is/are pending in the application.

Of the above, claim(s) 7-12 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-6, 13-16, and 49-52 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

The undersigned Examiner supports the effort on the part of the U.S. Patent Office to expedite prosecution as is reasonably possible. To that end Applicant is urged to submit all references deemed pertinent to the prosecution of the subject application without delay.

The present application is a continuation of S.N. 08/787,056, now abandoned. The file of the parent case is unavailable for review at this time. A response to the request for an election of species filed January 7, 2000, Paper No. 3, is acknowledged. Claims 17-48 are canceled and new claims 49-52 are presented. Accordingly, claims 1-16 and 49-52 are now under consideration.

On page 1 of Paper No. 3, an insertion to the specification on page 11, line 33, after "coronary artery disease" is noted. Such an amendment is not possible. Clarification is requested. On page 5 of Paper No. 3, Applicant elected the species atenolol "of amended claim 6" as the pharmacologic cardiovascular agent. It is noted claim 6 is not amended.

*(1) Note —* Following the election of atenolol without traverse, claims 7-12 are withdrawn from consideration by the Examiner as being drawn to non-elected inventions, 37 CFR 1.42(b).

Claims 1-6, 13-16 and 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

*(2) ND* Claims 1 and 49 are vague and indefinite with respect to recitations of heart rate and blood pressure, respectively, "greater than or equal to 65 bpm" and "greater than or equal to 100 mm Hg". Upper limits should be recited.

Art Unit: 1614

In claim 49 it is unclear whether or not parts a and b should be separated by "or".

Clarification is required.

Claim 52 appears to be missing language (possibly such as "is seen") at the end of the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*(3) minhajil*  
Claims 1-6, 13-16 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al., J. Cardiovasc. Pharmacol. (abstract) *in view of Katalia*

Goldstein teaches the administration of a therapeutic dose of the  $\beta_1$ -selective blocking agent atenolol to patients following cardiac-related surgery. Atenolol decreased both heart rate and blood pressure. The claims differ in that Goldstein fails to disclose the absence of congestive heart failure, third degree block or bronchospasm, as well as a specific heart rate and blood pressure reading at the time of dosing. However, one skilled in the art of cardiology would have been motivated to administer atenolol to reduce cardiovascular complications following surgery in view of the teachings of Goldstein. Such would have been obvious in the absence of evidence to the contrary because patients presenting with congestive heart failure, third degree heart block or bronchospasm are routinely not candidates for atenolol therapy. Further, a heart rate at or slightly above 65 bpm and a systolic blood pressure reading slightly over 100 mm Hg would be

Art Unit: 1614

considered within the normal range. The selections of both an optimal heart rate and systolic pressure at which time atenolol should be administered are parameters well within the purview of the skilled cardiologist through no more than routine experimentation. It would have been reasonable to expect atenolol to be effective for reducing cardiovascular disease complications following non-cardiac related surgery because atenolol is well established in the prior art as an effective agent for decreasing heart rate and blood pressure.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

April 6, 2000



**PHYLLIS SPIVACK  
PRIMARY EXAMINER**